## VII. 510(k) Summary

APR 23 2008

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

### A. Submitted by

Catherine Charles
Director of Regulatory Affairs and Quality Assurance
Sedat
135, Route Neuve
69540 Irigny – France
Telephone: +33 472 397 414
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### B. Device Name

Trade or Proprietary Name: *Sedat Myshell Lite*
Common or Usual Name: Myshell Lite Y Connector
Classification Name: Cardiopulmonary Bypass Adaptor, Stopcock, Mannifold, or Fitting
Device Class: Class II
Classification: 870.4290
Product Code: DTL

### C. Predicate Devices

The subject device is substantially equivalent to the Myshell device cleared under K040498.

### D. Device Description

The *Sedat Myshell Lite* consists of a variety of Y-connectors with a double silicone haemostatic valve within a reduce volume, well fitted for handling interventional procedures. The valve opening/closure mechanism could be activated by the thumb like a control button transforming the resilient valve in a variable geometry permitting to enlarge the valve opening of the silicone membrane. The interventionists make better adjustments for the seal introduction point and the size of the vascular instruments able to be introduced or removed to suit the individual pathology and anatomical conditions of the patient.

### E. Intended Use

The Sedat *Myshell Lite* is indicated for assisting, manipulating and maintaining a seal around diagnostic/interventional devices with an outside diameter<9F (<.098'') use in interventional angioplasty procedures.

### F. Substantial Equivalence

Data were provided which demonstrated the *Sedat Myshell Lite*, Y connector with a double silicone haemostaticvalve to be substantially equivalent to previously cleared

devices. The substantial equivalence is based upon equivalence in indications for use, design, material, and function.

**G. Summary of Non-Clinical Tests**
Bench performance testing was presented.

**H. Summary of Clinical Tests**
(Not Applicable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

SEDAT
c/o Ms. Laetitia Cousin
President
c/o EXCAELIA™
8895 Towne Centre Drive, 105-416
San Diego, CA 92122

Re: K080472
SEDAT MYSHELL LITE
Regulation Number: 21 CFR 870.4290
Regulation Name: Adapter, stopcock, manifold, fitting, cardiopulmonary bypass
Regulatory Class: Class II (two)
Product Code: DTL
Dated: February 20, 2008
Received: February 21, 2008

Dear Ms. Cousin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K080472

Device Name: SEDAT MYSHELL LITE

Indications For Use:

The SEDAT MYSHELL LITE is indicated for assisting, manipulating, and maintaining a seal around diagnostic/interventional devices with an outside diameter <9F (<.098") used in interventional angioplasty procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Donna R. Kochman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080472